

IN THE UNITED STATES RECEIVING OFFICE (RO/US)

Applicant: Lavipharm, S.A.
Int'l Application No: PCT/US04/05602
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Title of Invention: Devices for Releasing Volatile Substances and Methods
of Producing the Devices
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Commissioner for Patents
BOX PCT
Alexandria, VA 22313
Attn: IPEA/US

FORMAL RESPONSE UNDER PCT RULE 66.3

With respect to the Written Opinion dated 26 October 2004 (the "Opinion"),
Applicant responds as follows:

The Opinion states that claims 1, 4, 19-20, 22-24, 26-30, 32-35, 38-40, 42-44, 46-54, 56-59 and 68-69 lack novelty under PCT Article 33(2) as being unpatentable over Copley Pharmaceutical Inc (D1), Kanios (D2), and Cal Int. Ltd (D3).

Claim 1 of the instant application is directed to a method for making *an active layer to deliver a volatile substance*. The volatile substance is the active ingredient in the active layer and as it is volatile, it is delivered *to the environment* rather than to the subject. The Written Opinion acknowledges that the volatile substance is delivered to the environment in the claimed invention on the bottom of Separate Sheet 1 through the top of Separate Sheet 2.

Claim 38 of the instant application is drawn to a "device for delivering a volatile substance comprising: an *active* layer that is a dried polymer solution having *the volatile agent*, and a first release liner in direct contact with the active layer and covering a side of the active layer."

Reference D1 teaches a *transdermal* drug delivery system (a patch) for delivering a drug *to a subject* and methods for topically delivering a medicinal agent *to a subject* (see D1, p. 1, lines 4-6 and p. 15, lines 7-16). The evaporable substances

(i.e. volatile substance) in reference D1 is the solvent, and is specifically defined to be not the active ingredient (see p. 9, lines 17-24 and p. 14, lines 1-7, particularly line 4 - i.e., "the alcohol evaporates").

Reference D2 similarly teaches a *transdermal* drug delivery system for delivery of an active agent, and method of prolonged transdermal administration of a therapeutically effective amount of one or more active agents *to a subject*, wherein the active agent is delivered *through the skin or mucosa* of the user (see D2, p. 1, first para. of Background and claim 14). As in reference D1, the volatile liquids in D2 are solvents (see p. 26, 1st and 2nd para.) which do not "negatively affect the adhesive properties of the transdermal system or the solubility of the active agents", and they are by no means the active ingredients themselves.

D3 likewise teaches a *transdermal* patch for delivering an active ingredient *to a subject* (see D3, p. 2, line 26 through p. 3, line 1 ("In one aspect, the invention provides a transdermal patch for sustained transdermal administration of a pharmaceutical product *to a patient.*")).

In contrast, the presently claimed subject matter is not directed to a *transdermal* patch, a *transdermal* delivery system, a patch for topically administering a medicinal agent *to a subject*, or a method of making such systems or patches. The instant claims are directed to a method of making *an active layer* to deliver a *volatile* substance and a device for delivering a *volatile* substance. None of references D1, D2 or D3 teaches a method, or patch, or device, for delivering a *volatile* substance. Unlike in cited references D1, D2 and D3, the volatile substance in the instant application is the *active* ingredient in the active layer, it is not the solvent.

Since references D1, D2 and D3 all teach transdermal systems and patches for delivery of an active agent to a subject or patient, and none teaches non-transdermal delivery of a *volatile* substance, or a method of making an active layer to deliver a *volatile* substance, pending claims 1, 4, 19-20, 22-24, 26-30, 32-35, 38-40, 42-44, 46-54, 56-59 and 68-69 are novel over references D1, D2 and D3 and considered patentable over these references.

The Opinion further states that claims 1-36 and 38-69 lack Inventive Step under PCT Article 33(3) as being unpatentable over references Lavipharm SA (D4), Minnesota Mining & Mfg (D5), Kendall & Co. (D6), Zaffaroni (D7), or Avery Denison Corp (D8).

Reference D4 teaches a patch, and methods of making the patch, having a breathable layer, a barrier layer, an active volatile agent within a solid layer, and a release liner removably adhered to the barrier layer (see D4, claim 1). Moreover, the solid layer (and thus the volatile agent) is positioned between the barrier layer and the breathable layer and the barrier layer is impermeable to the volatile agent. Additional embodiments teach that the solid layer is non-hydrophilic (see Claim 2).

Claim 38 of the instant application (and the method of making an active layer – see Claim 1) is drawn to a device for delivering a volatile substance comprising an active layer that is a dried polymer solution having the volatile agent, and a first release liner in direct contact with the active layer and covering a side of the active layer. Importantly, there are no claims to a breathable layer between the release liner and the active layer. As claimed in method claim 1, the polymer including the volatile substance is applied “to a side of a first release layer” (see claim 1) and if a barrier layer is present, the barrier layer is attached “to the opposite side of the active layer from the first release liner” by an adhesive layer (see dependent claims 2, and 4 and others which depend from claim 4.) Similarly, all devices claimed required “a first release liner in direct contact with the active layer, and covering a side of the active layer” (see claim 38) as do all patches claims, which depend from claim 38 (see claim 56). In all examples claimed, the release liner is in direct contact with the active layer. Other embodiments require that the polymer solution is hydrophilic (see claim 39). This is directly contradictory to the solid layer of D4 being non-hydrophilic.

Additional references D5, D6, D7 and D8 do not teach or suggest any elements, alone or in combination with D4, that would lead one of ordinary skill in the art to arrive at a method for making an active layer, or a device or patch for delivering a volatile substance as claimed in the instant application - a device having

a first release liner in direct contact with the active layer, and covering a side of the active layer - and, as more particularly claimed, as having an active layer that is a *hydrophilic* polymer solution.

D5 teaches a composite tape structure and methods for making the tape – a double-sided tape. D6 teaches an adhesive tape, particularly bandages, for application to the skin. D7 teaches adhesive medical bandages for application to the skin, which also deliver a continuous supply of a vasodilator to the subject. D8 discloses a tape with an adhesive-inhibiting masking or barrier. There would be no motivation to combine references D5, D6, D7 or D8 singly, or together, with reference D4 because the instant claims are distinguishable from D4, as described above, and the combination of D4 with D5 and/or D6 and/or D7 and/or D8 would not allow a person of skill in the art to make the claimed active layer or device/patch containing the claimed active layer.

Claims 1-36 and 38-69, directed to a device that requires the first release liner to be in direct contact with the active layer, and a method of making an active layer for such a device, are neither taught nor suggested by D4 alone or in combination with any of the secondary references D5-D8, and therefore claim patentable subject matter.

Reconsideration of the application in light of the foregoing clarification is now requested in the international preliminary examination report.

Respectfully submitted,



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